CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

August 9, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket Number 1998N-0359, CFSAN Program Priorities for FY 2005, 69 Fed. Reg. 35380 (June 24, 2004)

INTRODUCTION

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the Food and Drug Administration (FDA) FY 2005 program priorities for the Center for Food Safety and Applied Nutrition (CFSAN).[1]

- **Seafood safety**

  1) *Vibrio vulnificus*

The FDA has established as one of its "A" level priorities for FY 2004 continuing to work with the Interstate Shellfish Sanitation Commission (ISSC) to implement a control strategy for *Vibrio vulnificus* in raw oysters (sub-strategy 1.5.5). While we agree that a control strategy for *Vibrio vulnificus* must be a priority, we disagree that FDA should be looking to the industry-dominated ISSC to resolve this problem. In the Healthy People 2010 Progress Review, FDA noted that the incidences of some foodborne infections are increasing, and that "[a] major challenge is finding ways to reduce the incidence of infections caused by *Vibrio* species" and

[1] CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by subscribers to its *Nutrition Action Healthletter*.

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other pathogens.[2] However, in October 2002, FDA denied CSPI's citizen petition requesting that the Agency establish a performance standard requiring the reduction of *Vibrio vulnificus* to nondetectable levels in raw molluscan shellfish. According to FDA, its best course of action is to continue to work with the ISSC, which adopted a strategy for *Vibrio vulnificus*.[3] The ISSC's plan, however, continues to rely on consumer education as its primary strategy and would not impose any post-harvest controls, if any, until 2007.[4]

Consumers continue to become ill and die from *Vibrio vulnificus* related to consumption of raw Gulf oysters. Between 1998 and 2000, 92 illnesses and 52 deaths linked to *Vibrio vulnificus*-contaminated raw shellfish were reported by public health officials.[5] Since January 2002, there have been at least 49 reported cases of *Vibrio vulnificus* due to consumption of raw shellfish, resulting in 24 deaths.[6] According to the preliminary FoodNet data for 2003, the incidence of *Vibrio* infections, including *Vibrio vulnificus*, has increased 116%.[7]

Because of FDA's failure to exercise leadership in this area, the California Department of

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[2] FDA, FSIS, CDC, *Healthy People 2010 Focus Area Data Progress Review*, Focus Area 10: Food Safety, Challenges, Barriers, Strategies and Opportunities, Section 10-1 (May 11, 2004) [hereafter *Health People 2010 Progress Review*].

[3] Letter to Michael F. Jacobson, Executive Director, CSPI, from John M. Taylor, III. Senior Associate Commissioner for Regulatory Affairs (Oct. 21, 2002).

[4] ISSC Final Report, *National Education Program to Influence Consumption Behavior of High-Risk Individuals Regarding Raw Molluscan Shellfish*, Phase III Final Report, at p. 1.

[5] FDA, Shellfish-Related *Vibrio vulnificus* Case/Deaths, 1989-2000.

[6] FDA, Shellfish-Related *Vibrio vulnificus* Case/Deaths, 2000-2002 (obtained through Freedom of Information Act request); FDA, Shellfish-Related *Vibrio vulnificus* Cases/Deaths, 2003 (obtained by the Office of Congressman Henry Waxman, California).

[7] CDC, Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – Selected Sites, United States, 2003, 53 *Morbidity and Mortality Weekly Report*, 338-343 (Apr. 30, 2004).

Health Service last summer adopted an emergency regulation to restrict the sale of raw oysters harvested from the states bordering the Gulf of Mexico from April through October, unless the oysters are treated with a scientifically validated process to reduce *Vibrio vulnificus* to non-detectable levels. Consumers can no longer afford to have the FDA defer to the ISSC, an industry-dominated organization. The Agency has the authority - and the obligation - under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act to protect consumers from this deadly pathogen.

Although FDA has rejected CSPI's petition to establish a performance standard for *Vibrio vulnificus*, FDA should reconsider that decision and make one of its top priorities establishing a performance standard for *Vibrio vulnificus*.

2) *Establish microbial testing program for hazards in seafood products*

FDA has classified as a "B" priority level review of CSPI's 2002 petition requesting FDA to establish a microbial testing program for hazards in seafood products (sub-strategy 1.5.12).[8] This petition requests FDA to design a mandatory government program to test not only for the levels of methylmercury in large predatory finfish, but also for *Listeria monocytogenes* in ready-to-eat fish and shellfish, the levels of ciguatera in tropical and sub-tropical reef fish, and the presence of *Vibrio* specifies in raw shellfish. Review of CSPI's petition should be elevated to an "A" priority because contaminated seafood continues to be a critical public health problem. CSPI has documented 720 seafood outbreaks with a known etiology that occurred between 1990 and 2003, the largest number of outbreaks from any other food source.[9] FDA's own evaluation

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[8] CSPI, *Petition for Regulatory Action to Establish a Microbial Testing Program for Hazards in Seafood Products* (Oct. 9, 2002).

[9] *See* CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* (revised. Mar. 2004).

of the Seafood HACCP Program for Fiscal Years 2000/2001 has identified continued problem areas, including control of pathogens by processors of cooked, ready-to-eat seafood and smoked seafood and control of scombrotoxin by processors of scombroid species.[10]

- **Fruits and Vegetables**

FDA lists as an "A" priority developing a strategy for addressing outbreaks caused by pathogens in fresh produce (sub-strategy 1.6.7). According to CSPI's database of foodborne illness outbreaks, there have been 428 outbreaks with 23,857 cases linked to produce and produce dishes between 1990 and 2003. In fact, more cases are attributed to produce than any other type of food.[11]

While we agree that this should be an "A" strategy, we disagree with FDA's approach, which appears to continue to rely on applying voluntary Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) to fresh produce production. The best way to minimize or prevent contamination is through implementation of mandatory hazard identification and process control systems, starting with the highest risk products first – those that have been repeatedly linked to illness outbreaks.

To that end, FDA should identify as an "A" priority the development of regulations that require growers, processors and others in the fresh produce supply chain to have written plans that identify hazards associated with their product and the steps, interventions, and programs taken to address those hazards. Mandatory process control systems would force all producers and processors to focus on the hazards associated with their products and have written plans in

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[10] FDA, Center for Food Safety and Applied Nutrition, *FDA's Evaluation of the Seafood HACCP Program for the Years 2000/2001* (Sept. 30, 2002).

[11] CSPI, *Outbreak Alert!* (Revised Mar. 2004).

place to identify where contamination is likely to occur and how to address it. It targets resources to critical areas and reduces risk based on prevention - the first goal of the proposed action plan.

- **Egg safety**

CSPI has long advocated a mandatory national farm-to-table egg safety program to address the public health threat of *Salmonella* Enteritidis (SE) in raw or undercooked eggs. Outbreak data compiled by CSPI show that eggs have been implicated in 266 SE outbreaks between 1990 and 2003.[12]

As an "A" priority, FDA lists the issuance of a proposed egg safety rule to further reduce human illnesses from SE (sub-strategy 1.7.1). We anticipate, based on meetings with high FDA officials, that this proposed rule will be published shortly. However, the 2004 Program Priorities does not include final action by FDA on the proposed rule as a priority.

FDA should list as an "A" priority publication of a final egg safety rule during the fiscal year. Consumers have waited long enough for FDA to adopt on-farm controls for shell eggs. We encourage FDA to take final action on the proposed egg rule during this fiscal year, particularly a rule that will implement and enforce proven SE control programs, such as measures that include environmental testing and diversion after an SE-positive result.

- ***Listeria***

Listeria monocytogenes remains one of the most serious foodborne pathogens. It is associated with higher hospitalization rates than any other pathogen and has an estimated 20%

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[12] CSPI, *Outbreak Alert!* (Revised Mar. 2004).

case fatality rate.[13] According to the preliminary FoodNet data for 2003, the incidence of *Listeria* did not continue to decline in 2003, as was observed during the preceding 4 years.[14]

In September 2003, FDA, with USDA and CDC, published a risk assessment on foodborne *Listeria monocytogenes* in certain categories of ready-to-eat foods. Foods regulated by the FDA, including unpasteurized fluid milk, smoked seafood, and cooked ready-to-eat crustaceans were classed as high risk foods for listeriosis. Moderate risk foods include high fat and other dairy products, soft unripened cheese, and pasteurized fluid milk.[15]

Nonetheless, FDA has only identified as "B" priorities the development of draft guidance advising processors on steps to reduce *Listeria monocytogenes* contamination in ready-to-eat food (sub-strategy 1.8.3), developing *Listeria* guidance for the dairy industry (sub-strategy 1.8.5), and performing target inspections of diary products manufacturers with an emphasis on those that produce milks, creams, butters and other products susceptible to *Listeria* contamination (sub-strategy 1.8.6). These should be elevated to "A" priority levels.

Moreover, FDA needs to go beyond mere guidance and adopt a regulatory response. Over the past 10 years, outbreaks of listeriosis have been documented in FDA-regulated foods, including chocolate milk and queso-fresco cheese. The chocolate-milk outbreak sickened 69

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[13] Mead, *et al., Food-Related Illness and Death in the United States*, Emerging Infectious Diseases 5(5): 607-625 (1999).

[14] CDC, Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – Selected Sites, United States, 2003, 53 *Morbidity and Mortality Weekly Report*, 338-343 (Apr. 30, 2004).

[15] FDA, USDA, CDC, *Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods, Interpretative Summary* (Sept. 2003), at p. 12.

individuals living in three states.[16] In the queso-fresco cheese outbreak, there were 12 reported cases. Ten of these cases were pregnant women, five of whom lost their babies due to stillbirths.[17] Now that FDA has completed the risk assessment, it should make it a priority to require plants producing FDA-regulated foods at risk for *L. monocytogenes* (such as soft cheese, pasteurized and unpasteurized milk products, seafood products, and prepared salads) to test their environments and final products for the presence of the pathogen.

- ***Transmissible Spongiform Encephalopathies*** **(TSEs)**

FDA has listed as an "A" priority the publication of a BSE regulation banning the use of bovine specified risk materials, nonambulatory disabled and dead cattle, and mechanically separated beef in FDA-regulated products (sub-strategy 1.11.1). FDA has accomplished this priority by publishing an interim final rule in the Federal Register on July 14, 2004.[18]

On the same day, FDA also published two other notices in the *Federal Register*: 1) a proposed rule requiring manufacturers and processors of food and cosmetics to keep records demonstrating that prohibited materials from cattle are not used in their products;[19] and 2) an advanced notice of proposed rulemaking (ANPRM) seeking comment on several measures related to the ruminant feed ban.[20] Yet, CFSAN includes neither the proposed rule nor the ANPRM in its priorities list. This signals that CFSAN does not intend to take final action on

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[16] CDC, *U.S. Foodborne Disease Outbreaks*, available at <*http://www.cdc.gov/ncidod/dbmd/oubreak/us_outb.htm*>.

[17] CDC, "Outbreak of Listeriosis Associated with Homemade Mexican-Style Cheese - North Carolina, October 2000-January 2001," 50 *Morbidity and Mortality Weekly Report*, pp. 560-62.

[18] 69 Fed. Reg. 42,255 (July 14, 2004).

[19] 69 Fed. Reg. 42,275 (July 14, 2004).

[20] 69 Fed. Reg. 42,287 (July 14, 2004).

these notices during the fiscal year, and that they are not considered agency priorities. However, both of these actions are crucial in FDA's effort to strengthen safeguards to protect Americans from exposure to the BSE agent.

FDA cannot delay on finalizing the recordkeeping rule and on taking action to strengthen the ruminant feed ban. Therefore, the agency should revise its Priorities List with respect to TSEs and add final promulgation of both the proposed rule and the ANPRM as "A" priorities.

- **Acrylamide**

Acrylamide contamination may be causing both thousands of cases of cancer per year in the United States and some less-quantifiable risk of neurologic illnesses. On June 4, 2003, CSPI filed a petition with FDA asking that it immediately establish interim acceptable levels for acrylamide in major food sources (docket number 03P-0276). On June 27, 2003, CSPI filed a comment in a proceeding on infant formula (docket number 95N-0309) asking that FDA immediately test every brand of infant formula to determine whether it contains detectable levels of acrylamide and then convene a workshop to make recommendations to the FDA on how to reduce, if not eliminate, acrylamide in all infant formulas. The FDA gave an "A" priority in FY 2004 to analyzing selected food samples for acrylamide (sub-strategy 1.10.1).

These two regulatory matters – which are not even mentioned in FDA's FY 2004 Program Priorities – should be an "A" priority in FY 2005.

- **Potassium Bromate**

The FDA has known since 1982 that potassium bromate can cause tumors of the kidney, thyroid, and other organs in animals. Subsequent studies on rats and mice confirmed that it can cause such tumors. On July 19, 1999, CSPI petitioned the FDA to ban bromate. FDA listed bromate as a "B" priority in its 2004 Program Priorities (sub-strategy 2.1.3), explaining that the

Agency would "continue work on developing a strategy for regulating the use of bromates in baked goods and to respond to the pending citizen petition." In its latest priority list, however, FDA has downgraded the importance of the problem, although the "B" designation remains unchanged. Now it states that it will "continue to *monitor* the use of bromates in baked goods." (Sub-part 3.1.2.h) (*emphasis added*) Responding to the pending petition is, thus, no longer on FDA's radar screen. We urge that this matter be given higher priority.

- **Sorbitol and Mannitol**

In September 1999, CSPI petitioned the FDA to require foods containing one or more grams per serving of sorbitol or other sugar alcohol, such as mannitol, to carry a better warning label that the foods may cause severe diarrhea and are not suitable for consumption by children.[21] The use of these sugar alcohols has skyrocketed in the past several years, because of the increased sales of low-carbohydrate foods. The FDA should accord this petition priority attention.

- **Salatrim**

As discussed in our 1998 petition to the FDA, salatrim may cause diarrhea in humans and products containing this ingredient may be misbranded.[22] The FDA has taken no action on this matter. We urge that it be given priority attention.

- **Infant Formula**

On July 9, 1996, FDA issued a proposed rule to establish requirements for current good manufacturing practices and audits, establish requirements for quality factors, and amend its

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[21] *Petition to Improve the Existing Warning Label on Processed Foods that Contain the Sugar Substitute Sorbitol* (Sept. 27, 1999).

[22] *Petition to FDA on the Generally Recognized as Safe (GRAS) Status of Salatrim* (June 19, 1998).

quality control procedures, notification, and records and reports requirements for infant formula. Nearly seven years later, FDA reopened the comment period to receive new information.[23] While this rulemaking was pending, there was an outbreak of E. Sakazaki among 10 infants in a Tennessee hospital. One of them died.[24] Despite the importance of maintaining the highest quality in infant formula – the sole source of nourishment for many infants – FDA considers a final GMP rule a "B" priority (sub-strategy 2.1.3.c). Considering that last year, reopening the comment period was an "A" priority, it makes little sense to downgrade completion of the rulemaking process to a "B" priority.

- **Carmine/Cochineal Extract**

CSPI is pleased that the Agency has upgraded from a "B" to an "A" priority the development of a proposed rule to require the declaration of carmine/cochineal extract, a color additive, on products containing it (sub-strategy 1.13.4). As we stated in our 1998 petition, carmine/cochineal extract may cause severe allergic reactions in humans.

- **Quorn Mycoprotein**

We urge the FDA to give priority attention to banning the sale of this product for the reasons set forth in our numerous letters to the Agency over the past 30 months. Although not even mentioned in FDA's FY 2004 priorities, this product has caused serious health problems including anaphylaxis, severe vomiting, and diarrhea. It should be removed from the market in FY 2005.

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[23] 68 Fed. Reg. 22,341 (Apr. 28, 2003).

[24] *Id.*

- **Allergens**

In July 2004 Congress passed S. 741, which contains – as Title II – the Food Allergen Labeling and Consumer Protection Act of 2003; the President signed this bill on August 2, 2004 (P.L. 108-282). One part of this law directs the FDA to submit a report to Congress within 18 months analyzing how foods are inadvertently contaminated with major food allergens and how consumers with food allergies would prefer that information about such cross-contact be communicated on food labels. The law also requires the FDA to report on its allergen inspections of food-processing plants, including the number of inspections and the number of violations. The House report on the bill directs the FDA to work with the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury to promulgate allergen labeling regulations for alcoholic beverages.[25]

The report, the inspections, and the alcoholic beverage regulations should all be "A" priorities for FY 2005.

- **Preventing Obesity through Better Nutrition**

One of the most important health problems today is the rapid increase in the number of individuals who are overweight and obese. While the FDA has limited authority over restaurant labeling and is, therefore, unable to take all the necessary steps to combat this problem, it should take advantage of whatever leverage it has to support legislation dedicated to reducing the obesity epidemic. The FDA should not simply implement a voluntary program for restaurants to list nutrition information for their patrons (sub-strategy 2.1.1.j). Instead, the FDA should ask the Department of Health and Human Services (HHS) to support legislation requiring chain

[25] H.R. Rept. 108-608, 108th Cong., 2d sess. (2004) at 3.

restaurants to provide calorie information on menu boards and information about calories, saturated and trans fat, and sodium on printed menus.

CSPI is pleased that the FDA has established as "A" priorities publishing an ANPRM to solicit comment on establishing proper serving sizes on food packages (sub-strategy 2.1.1.e) and issuing letters to manufacturers regarding inaccurate serving sizes (sub-strategy 2.1.1.i). These actions are urgently needed because many people unwittingly eat several servings at a time and assume they have consumed only the calories in one serving. In order to be effective, the nutrition facts label must include a serving size that accurately reflects the amount of food a typical consumer would consume in a single serving.

CSPI is pleased that the FDA has established as "A" priorities developing consumer messages with a "calories count" focus (sub-strategy 2.1.1.c) and publishing an ANPRM to solicit comment on how to give more prominence to calories on the food label (sub-strategy 2.1.1.d). The FDA should study whether listing the calorie content per serving and per package in larger, bolder type might encourage people to pay more attention to calories. The FDA should elevate to an "A" priority the development of an ANPRM to solicit comments on whether to allow a health claim such as "Diets low in calories may reduce the risk of obesity, which is associated with diabetes, heart disease, and certain cancers" on certain foods (sub-strategy 2.1.1.g). Displaying such a message prominently on certain food packages would encourage consumers to choose more healthful foods and encourage consumers to develop more low-calorie products.

- **Nutrient Content Claims for Carbohydrates**

In 2004, the Grocery Manufacturers of America, Con Agra and CSPI filed petitions asking the FDA to issue a nutrient content claim regulation defining the term "low

carbohydrate." Spurred by the popularity of the Atkins and South Beach diets and the absence of FDA action, carbohydrate manufacturers have developed a series of synonyms – e.g. carb counting, carb smart, carb aware, carb control and carb options – to convey the impression that the products are low in carbohydrates. Furthermore, these claims are often based on different methods of calculating carbohydrate content declared as net carbs, impact carbs or similar terms on the label. These claims are confusing to consumers and thwart the Nutrition Labeling and Education Act's goal of developing a "limited lexicon" of terms that consumers can rely on to understand the nutrient content of the foods they eat.

Until such time as FDA defines permissible carbohydrate claims and appropriate synonyms, consumers will be misled. Moreover, FDA is sending a message to manufacturers that FDA is not proactive and that they may respond to popular diet trends by making claims consistent with those trends regardless of whether such claims have been approved by the FDA. FDA's decision to set a "B" priority for use of the term "net" in relations to the carbohydrate content of foods (sub-strategy 2.1.1.f) is inappropriate and shortsighted.

- **Caffeine**

In 1997, both the American Medical Association and CSPI asked the FDA to require that the amount of caffeine in foods be declared on the label. The July 2003 *Consumer Reports* published a story disclosing the hidden amounts of caffeine in various foods and discussing the possible health consequences of caffeine on children – nausea, vomiting, diarrhea, cramps, and muscle twitching. In addition, both the FDA and physicians advise pregnant women to avoid caffeine or consume only small amounts because of the correlation between the daily consumption of several cups of coffee with low birth weight, miscarriages, and other adverse effects on pregnancy.

CFSAN recently conducted a survey of available data bases to determine the prevalence of caffeine in the food supply. At the March 11, 2004 hearing on the FDA's FY 2005 budget, Deputy Commissioner Crawford told Representative Farr that caffeine labeling would be put on the agenda of the FDA's Food Advisory Committee. The FDA subsequently told Representative Farr that it has "decided to conduct a second survey to look at foods that were not represented in the databases. The agency is utilizing a contractor to conduct this survey and will analyze the data when the survey is completed."[26] The FDA made "developing a policy on caffeine labeling" only a "B" priority for FY 2004 (sub-strategy 2.1.4.e).

CFSAN should make it an "A" priority for FY 2005 both to complete this survey and to have the Food Advisory Committee consider the matter so that the FDA can promptly initiate a rulemaking to require that the amount of caffeine in foods be disclosed.

- **Functional Foods**

The FDA should enforce the food additive provisions of the law and prevent companies from adding herbal medicines and other novel ingredients to foods that are not Generally Recognized as Safe (or approved as food additives). Dietary supplements must not be allowed to masquerade as foods in order to avoid sections of the law pertaining to food additive approval. Thus we support substrategy 3.1.2.a and urge that it remain an "A" priority.

The FDA should also respond to the CSPI petition seeking implementation of the recommendations contained in a report by the General Accounting Office (GAO).[27] Among its numerous recommendations, the GAO report concluded that regulations should be adopted on

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[26] *Hearings on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2005*, Part 3 (2004) at 325.

[27] CSPI, *Petition for Rulemaking on Functional Foods and Request to Establish an Advisory Committee*, Docket No. 02P-0122/CP1. Mar. 21, 2002.

the safety-related information required on labels; the nature and extent of evidence companies need to adequately support structure/function claims; a notification procedure prior to the use of novel ingredients; and the use of the same disclaimer as is currently required on dietary supplements. It also called for the establishment of an advisory committee to reevaluate the current labeling approaches for foods with novel ingredients to determine whether the distinctions between structure/function and health claims are understood by consumers and identify other changes needed to improve consumer understanding of health-related claims.

- **Dietary Supplements**

We support maintaining sub-strategy 2.2.4, which is to take enforcement action against supplement ingredients that raise safety problems, as an "A" priority. We also support efforts by the Agency to initiate targeted research programs on dietary supplements (sub-strategy 4.1.5) where there are significant safety concerns. Further, the FDA should expand the National Academy of Sciences' study of dietary supplement safety. More products should be covered, and the study should be expanded to efficacy as well.

The FDA is burdened with a weak law that limits its authority to protect the public from unsafe and misleadingly labeled supplements. Recently, members of Congress have introduced or called for new legislation. The FDA should, upon request, provide information detailing the need for a new approach to dietary supplement regulation, including the need for explicit statutory authority to impose mandatory adverse event reporting requirements.

- **Impact of the Growth of International Trade on Food Safety**

The FDA should encourage the Administration to set trade policies that further the objectives of the Act. The FDA should ensure that public health takes precedence over trade concerns and should urge that international standards be harmonized upward. These factors

should be taken into account when the Agency takes positions on behalf of the U.S. government delegation to Codex meetings. The FDA should also issue analyses of the food safety implications of proposed free trade agreements.

- **Trans Fatty Acids**

The FDA should make it a top priority to: 1) propose new rules for putting in context the required disclosure of the amount of trans fatty acids on packaged foods and to regulate nutrient content and health claims involving packaged foods that contain trans fatty acids, and/or significant quantities of saturated fat, and/or cholesterol; 2) propose a rule to revoke the authority for industry to use partially hydrogenated vegetable oils in packaged and restaurant foods, as requested by CSPI in its May 18, 2004 petition (docket number 2004P-0236/CP1); and 3) require restaurants to indicate that the food they serve contains trans fat from partially hydrogenated vegetable oils, as requested by CSPI in its July 22, 2004 petition (docket number 2004P-0328).

All three of these matters should be made an "A" priority for FY 2005.

- **Sodium**

Cardiovascular-disease experts agree that diets high in sodium increase the risk of heart disease and stroke. In 2002, the American Public Health Association adopted a policy resolution calling for a 50% reduction in sodium in processed and restaurant foods over the next 10 years.[28] In a recent editorial in the American Journal of Public Health (January 2004), the former director of the National Heart, Lung and Blood Institute at the National Institutes of Health estimated that cutting sodium intake in half would reduce cardiovascular disease deaths by 150,000 per year.[29]

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[28] *Reducing the Sodium Content of the American Diet.* Washington, DC. American Public Health Association; 2002. Cited in Havas S, Roccella EJ, Lenfant C. Reducing the public health burden from elevated blood presure levels in the United States by lowering intake of dietary sodium. Am J Pub Health. 2004;94:19-22.

[29] *Ibid.*

Clearly, every bit of progress on this matter would save many more lives than just about anything else within the FDA's purview.

Twenty years ago, the FDA agreed that sodium was a top priority and added sodium to the "voluntary" nutrition label. However, at the same time, the FDA rejected CSPI's requests to remove sodium chloride from the GRAS list, require sodium labeling of all products, limit sodium levels in key categories of processed foods, and require a warning notice on large packages of salt. The FDA rejected all those measures, but said that if "voluntary" labeling did not deal with the problem adequately, it would consider stronger measures. Ten years later, at Congress's initiative, the Nutrition Labeling and Education Act was passed (1990) and required sodium labeling on almost all packaged foods (1994). Notwithstanding those labeling measures, along with FDA's own modest educational program in the early 1980s, sodium consumption has not decreased, but *increased*, over the past 20 years. In other words, the FDA has failed to protect the public from this hidden dietary scourge. Meanwhile, the evidence of sodium's harmfulness has become ever more solid.

It is urgent that the FDA make sodium-reduction a top priority. We recommend that FDA undertake measures now that it would not take 20 years ago: limit sodium levels in various categories of processed foods, require a warning notice on large packages of salt, and require a special warning notice on processed foods high in sodium (as well as on the menus of chain restaurants).

- **Added Sugars**

The FDA should give priority attention in FY 2005 to proposing a rule that would require the listing of amounts of both total and added-sugars content, along with the percentage of a newly designated Daily Value for added sugars as described in our previous petition to the

Agency. The grounds for this request are set out fully in CSPI's August 1999 petition to the Agency (docket number 99P-2630/CP1).[30]

- **Food Choking Hazards to Children**

The FDA should give priority attention to protecting young children from choking on foods by requiring companies to label certain products as potential hazards. Every year in the U.S., more than 70 children die from choking on food and more than 10,000 children are treated for such problems in emergency rooms. Some companies voluntarily label products (such as hard candies and other foods) as inappropriate for consumption by young children or provide label instructions on how the product should be prepared by parents (chopped, sliced, etc.) in order for it to be consumed safely. The FDA should establish a nationwide surveillance system on childhood food choking, and engage in educational outreach to parents, pediatricians, and hospitals. It should also require all food companies that sell products that constitute choking hazards to provide standardized safety instruction labeling.

- **Percentage Ingredient Labeling**

CSPI has petitioned the Agency to extend percentage-ingredient labeling to all foods. Quantitative Ingredient Declaration (QUID) is necessary for consumers to compare the relative amount of specific ingredients between seemingly similar products. In the EU, Australia, and New Zealand, QUID requirements are already in place. The FDA should work with the Working Group of the Codex Committee on Food Labeling that has been formed to develop an international standard for QUID. We note that the U.S. Department of Agriculture has recently

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[30] *Petition for Proposed Rulemaking to Establish a Daily Value for "Added Sugars," to Require Nutrition Labeling of "Added Sugars," and to Make Corresponding Changes to Nutrient Content and Health Claim Regulations,* (Aug. 3, 1999).

finalized a rule requiring percentage ingredient labeling of the meat component of frozen pizza. The FDA should expand its work in this area as well.

- **Misleading Ingredient Claims**

Enforcement of the FDA's food-labeling requirements has waned in recent years. As a result, misleading claims on food labels are increasing. We urge the Agency to enforce the law with particular attention to misleading claims pertaining to healthful ingredients such as whole wheat, fruits and vegetables. Violations of the Act that cannot be handled by the FDA because of resource constraints should be systematically delegated to state enforcement agencies.

- **Health Claims**

The FDA should delay the issuance of qualified health claims until consumer perception studies provide data about the most effective way to present such claims to consumers. The FDA should further propose implementing regulations for the health and nutrition claims sections of the Food and Drug Administration Modernization Act of 1997. Those regulations should require public docketing of all health claim notifications. In addition, such regulations should specify that health and nutrition claims based on authoritative statements of other government agencies are limited to statements that were intended to constitute dietary recommendations.

The FDA should cease approval of product-specific health claims for breakfast cereals and other specific foods. Such claims provide consumers with potentially misleading dietary advice that is not supported by the public health community.

- **Food Standards**

The FDA lists the development of a proposed rule on guiding principles for standards of identity as an "A" priority (sub-strategy 4.5.3). This matter should be dropped. The initiative is not supported by consumer organizations and some segments of the food industry. In an era of

limited resources, the effort should be terminated.

CONCLUSION

CSPI appreciates the opportunity to comment on CFSAN's priorities for FY 2005. The issues to which the FDA chooses to give priority attention will have a vital impact on the health and well-being of all Americans.

Sincerely,

Bruce Silverglade
Director of Legal Affairs

Aliza Sperling
Staff Attorney

CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

August 17, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket Number 1998N-0359, CFSAN Program Priorities for FY 2005, 69 Fed. Reg. 35380 (June 24, 2004)

To the Clerk:

Please find enclosed two copies of comments from the Center for Science in the Public Interest in the above referenced matter.

Please call (202) 332-9110, ext. 358 with any questions. Thank you.

Sincerely,

Aliza Sperling

Aliza Sperling
Staff Attorney